UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,580	09/23/2005	Martin F. Bachmann	1700.0610001/BJD/WBC	8355

26111 7590 05/11/2007

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
KINSEY, NICOLE	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
05/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,580	BACHMANN ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *4,6,7,9-11,49,94-96,98-99,102-104 and 108-110,112* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8,12,14,15,17,21,24,25,27,30,33,35,42,48,97 and 111* is/are rejected.

7)☒ Claim(s) *18 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-12,14,15,17-19,21,24-25,27,30,33,35,42,48,49,94-99,102-104 and 108-112.

DETAILED ACTION

Applicants' election with traverse of Group I (claims 1, 2, 4, 6-12, 14, 15, 17-19, 21, 24, 25, 27, 30, 33, 35, 42, 48, 87 and 111) and species RNA phages (Qβ), immunostimulatory deoxyribonucleic acids, and SEQ ID Nos: 71, 72 and 85 in the reply filed on March 9, 2007 is acknowledged. The traversal is on the grounds that i) Groups I and II share a special technical feature, ii) there is no search burden for Groups I-III or for the species, and iii) applicants are permitted to have at least 10 sequences searched. This is not found persuasive.

In response to traversal i), the technical feature shared among the inventions listed as Groups I and II is a composition comprising a virus-like particle; at least one immunostimulatory substance; and at least one antigen or antigenic determinant. The noted shared technical feature does not provide a contribution over the prior art, as evidenced by the teachings of Kozlovska et al. and Krieg et al. (see Restriction Requirement dated February 9, 2007 for an explanation as to how the combination of these prior art references teach the shared technical feature). Therefore, because the shared technical feature does not make a contribution over the prior art, unity of invention is lacking.

As for traversal ii), search burden (or lack thereof) is irrelevant when determining lack of unity in PCT applications and applications filed under 35 U.S.C. § 371.

As for traversal iii), according to the OG Notice dated March 27, 2007, the United States Patent and Trademark Office (Office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant

to 37 CFR 1.141 et seq. and for unity of invention determinations pursuant to 37 CFR 1.475 et seq. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten, independent and distinct molecules described by their nucleotide sequence in a single patent application. The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention determination will be made in view of PCT Rule 13.2, 37 CFR 1.475 and Chapter 10 of the ISPE Guidelines. Unity of invention will exist when the polynucleotide molecules, as claimed, share a general inventive concept, i.e., share a technical feature, which makes a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Applicants further stated that the Examiner made a premature rejection under 35 U.S.C. § 103. This statement is not accurate. There were no rejections made in the Restriction Requirement. To the contrary, the Examiner made a showing, *a posteriori*, that the shared technical feature did not make a contribution over the combined prior art references.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8, 42 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 48 recite that the "at least two HIV polypeptides are bound directly or by way of a linking sequence." It is not clear if applicants intend the two polypeptides to be bound to each other directly or by way of a linking sequence or bound to the VLP directly or by way of a linking sequence.

Claim 42 recites the limitation "said palindromic sequence" in reference to claim 30. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 8, 12, 14, 15, 17, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. (U.S. Application No. 2003/0099668, filed September 16, 2002, with priority to September 14, 2001 and April 22, 2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to a composition comprising: a virus-like particle (VLP); at least one immunostimulatory substance; and at least one antigen or antigenic determinant; wherein said at least one antigen or antigenic determinant is bound to said virus-like particle, and wherein said immunostimulatory substance is packaged into said virus-like particle, and wherein said immunostimulatory substance is an immunostimulatory nucleic acid, and wherein said antigen comprises at least one HIV polypeptide.

Bachmann et al. discloses compositions comprising a virus-like particle, with immunostimulatory CpG oligonucleotides packaged in the virus-like particles and with antigens bound to the virus-like particles (see abstract and summary).

The antigen can be attached to the virus-like particle by covalent bonds (e.g., ester, ether, phosphoester, amide, peptide, imide, carbon-sulfur bonds, carbon-phosphorus bonds by chemically coupling) or non-covalent bonds (see paragraph [0120]). The antigen can be from infectious viruses such as HIV (e.g., HIV gp140 and gp160) (see paragraphs [0110], [0307] and [0335]), and the antigens can be a T-cell epitope or a combination of at least two epitopes, wherein the at least two epitopes are linked directly or by way of a linking sequence (see paragraph [0336]). The antigen can be bound to the VLP via a cross-linker containing a functional group which can react with a first attachment site (i.e., the side-chain amino group of lysine residues of the VLP or at least one VLP subunit) and a further functional group which can react with a second attachment site (i.e., a sulfhydryl group of a cysteine residue fused to the antigen or antigenic determinant) (see paragraph [270]). The VLPs are preferably made from the RNA phage Qβ (see paragraphs [0152] and [0162]-[0170]) or AP205 (see paragraphs [0177]-[0189]). The packaged CpG oligonucleotide is unmethylated and may comprise a palindromic sequence (see paragraph [0130]). The specific CpG oligonucleotide of SEQ ID NO:41 comprising the palindromic sequence of SEQ ID NO:1 is disclosed in Table I of Example 11. Bachmann et al. also discloses a vaccine composition comprising the VLPs as described above in a pharmaceutically acceptable

diluent, carrier or excipient. The vaccine can also optionally comprise an adjuvant (see paragraph [0341]).

Claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42, 48, 97 and 111 are rejected under 35 U.S.C. § 102(e) as being anticipated by Bachmann et al. (U.S. Application No. 2004/0005338, filed June 20, 2003, with priority to June 20, 2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are drawn to a composition comprising: a virus-like particle (VLP); at least one immunostimulatory substance; and at least one antigen or antigenic determinant; wherein said at least one antigen or antigenic determinant is bound to said virus-like particle, and wherein said immunostimulatory substance is packaged into said virus-like particle, and wherein said immunostimulatory substance is an immunostimulatory nucleic acid, and wherein said antigen comprises at least one HIV polypeptide.

Bachmann et al. discloses compositions comprising a virus-like particle, with immunostimulatory CpG oligonucleotides packaged in the virus-like particles and with antigens bound to the virus-like particles (see abstract and summary).

The antigen can be attached to the virus-like particle by covalent bonds (e.g., ester, ether, phosphoester, amide, peptide, imide, carbon-sulfur bonds, carbon-phosphorus bonds by chemically coupling) or non-covalent bonds (see paragraph [0081]). The antigen can be from infectious viruses such as HIV (e.g., gp140 and gp160) (see paragraphs [0218], [0219] and [0260]), and the antigens can be a T-cell epitope or a combination of at least two epitopes, wherein the at least two epitopes are linked directly or by way of a linking sequence (see paragraph [0261]). The VLPs are preferably made from the RNA phage Qβ (see paragraphs [0108] and [0118]-[0128]) or AP205 (see paragraphs [0138]-[0148]). The packaged CpG oligonucleotide is unmethylated and may comprise a palindromic sequence (see paragraph [0091]). The specific CpG oligonucleotide of SEQ ID NO:41 comprising the palindromic sequence of SEQ ID NO:1 is disclosed in Table I of Example 18. Bachmann et al. also discloses a vaccine composition comprising the VLPs as described above in a pharmaceutically acceptable diluent, carrier or excipient. The vaccine can also optionally comprise an adjuvant (see paragraph [0265]).

Double Patenting

Claims 1, 2, 8, 21, 24, 25, 27, 30, 33, 35, 42 and 48 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10, 14-16, 41, 48 and 55 of copending application 10/563,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because they relate to the same inventive concept. The instant composition claims are

obvious over the claims of the copending application because the claims of the copending application have all of the characteristics of the instant composition claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The elected species SEQ ID Nos: 71, 72 and 85 are allowable. Claims 18 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable, as they read on the elected species, if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

Stacy B. Chen 5/10/07
STACY B. CHEN
PRIMARY EXAMINER